K000606

MAY - 5 2000

BECKMAN COULTER

510(k) Summary
SYNCHRON® Systems
Amphetamine (AMPH) Reagent

1.0 **Submitted By:**

Lucinda Stockert
Staff Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-3777
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2.0 **Date Submitted:**

February 17, 2000

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Amphetamine Reagent

3.2 **Classification Name**

Amphetamines Test System (21 CFR §862.3100)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Amphetamine Reagent (PN 475000)	SYNCHRON® Systems Amphetamine Reagent (PN 445965)	Beckman Coulter, Inc.	K944604

5.0 **Description:**

The SYNCHRON® Systems Amphetamine Reagent is in a ready-to-use liquid format and packaged into bar coded cartridges that are placed directly onto the SYNCHRON Systems.

5.0 **Intended Use:**

The SYNCHRON Systems Amphetamine (AMPH) Reagent, in conjunction with the SYNCHRON System Drugs of Abuse (DAT) Urine Calibrators, is intended for use in the qualitative determination of amphetamine in human urine at a cutoff value of 1000 ng/mL, on SYNCHRON Systems.

7.0 **Comparison to Predicate(s):**

Same intended use and chemical reaction as the predicate. Mouse antibody source for each reagent is different.

8.0 **Summary of Performance Data:**

SYNCHRON CX AMPH Relative Sensitivity and Specificity

AMPH		475000 (new)		TOTAL
		Positive	Negative	
445965 (current)	Positive	44	6	50
	Negative	4	58	62
Total		48	64	112

Relative Sensitivity: 88%
Relative Specificity: 94%
Overall Agreement: 91%

SYNCHRON LX AMPH Relative Sensitivity and Specificity

AMPH		475000 (new)		TOTAL
		Positive	Negative	
445965 (current)	Positive	44	6	50
	Negative	4	58	62
Total		48	64	112

Relative Sensitivity: 88%
Relative Specificity: 94%
Overall Agreement: 91%

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to Opiate Test Systems already in commercial distribution.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 5 2000

Ms. Lucinda Stockert
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
W-104
P.O. Box 8000
Brea, California 92622-8000

Re: K000606
Trade Name: SYNCHRON® Systems Amphetamines Reagent
Regulatory Class: II
Product Code: DKZ
Dated: April 20, 2000
Received: April 25, 2000

Dear Ms. Stockert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **SYNCHRON® Systems**
Amphetamines Reagent

Indications for Use:

The SYNCHRON® Systems Amphetamines (AMPH) Reagent, when used in conjunction with SYNCHRON® Systems Drugs of Abuse Testing (DAT) Urine Calibrators, is intended for the qualitative determination of amphetamines in urine, at a cutoff value of 1000 ng/mL on Beckman Coulter's SYNCHRON Systems.

Clinical Significance:

An amphetamine test system is a device intended to measure amphetamine, a central nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.

Kim Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000602

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96